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EU-27

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report gives an overview of food laws currently in force in the EU-27. The following sections were updated/added: food laws, labeling requirements, warning labels, nutrition & health claims, nutrition labeling, country of origin labeling, food contact materials, additives, pesticides & contaminants, product inspection, fortified foods, special use foods, single common market organization, fruit & vegetables, wine, organic foods, pet food, trademarks, geographical indications, import procedures. European Commission proposals/initiatives which may have an impact on U.S. exports are also included.

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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service, U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Information on EU Member State specific requirements can be found in the FAIRS reports prepared by the Offices of Agricultural Affairs in the individual EU Member States:

<http://useu.usmission.gov/agri/fairsh.html>

SECTION I. FOOD LAWS

The European Union (EU) has gradually expanded to become the world's largest multi-nation trading bloc. Since January 1, 2007, the European Union comprises 27 member states with approximately 490 million consumers. EU member states: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom. Iceland, Croatia, the Former Yugoslav Republic of Macedonia and Turkey are candidates to join the EU.

All EU Member countries accept the "acquis", i.e. the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party, including the EU laws and rules pertaining to processed foods.

Originally created as a customs union, the process of harmonizing existing Member State legislation has been long and cumbersome and is still ongoing. While the vast majority of food laws and regulations have been harmonized throughout the EU, the single EU market is still not a "done deal". It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States. The FAIRS reports prepared by the Offices of Agricultural Affairs in the EU Member States are excellent sources of information on Member State specific requirements (<http://useu.usmission.gov/agri/fairs.html>).

The main principle of the single market concept is the "principle of mutual recognition" to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with the requirements. There is one exception to this principle: certain directives allow Member States to make exceptions e.g. in cases where a country can prove public safety, health or environmental concerns about a product intended for import. [Regulation 764/2008](#), adopted in July 2008, sets out the procedural requirements for denying mutual recognition and defines the rights and obligations of national authorities on the one hand and enterprises on the other. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the general labeling directive but may carry a health claim for which harmonized rules do not yet exist. Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation that covers aspects which are

common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.). EU food legislation is characterized by a constant flow of new regulations and directives, amendments to existing legislation and implementation rules. EU laws are translated into the 23 official languages in use in the EU-27 and published chronologically in the Official Journal. **Directives** define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). **Regulations** are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. Consolidated texts, i.e. the consolidation of a basic legal act and subsequent amendments into one text, are available on the European Commission's website but come with a warning that they are not legally binding. When legislation is referenced in this guide, it is implied that all further amendments also apply. Where possible, this guide links directly to referenced pieces of EU legislation. However, as legislative acts in pdf-format are only available as of 1995, links are not being established to legislation that was published before 1995. The Eurlex website (<http://eur-lex.europa.eu/en/index.htm>) provides free access to European Union law.

In the context of "Better Regulation" the EU is in the process of carrying out a "rolling simplification program". The main objectives of this program are the simplification of existing EU law and the introduction of a new regulatory approach. One of the main simplification tools consists in substituting directives with regulations. Under this new approach, the use of regulations instead of directives will help to eliminate the diverging interpretations by the different Member States and as regulations are directly applicable, Member States no longer need to go through the lengthy process of transposing into national laws. Another simplification tool is the codification and consolidation of legal acts and their amendments into a single text which is legally binding once published in the Official Journal.

In the aftermath of the BSE crisis and several other food scandals in the late 1990s, the EU developed a "Farm to Fork" approach covering all sectors of the food and feed chain, with traceability as basic concept. The application of the "precautionary principle" as described in the February 2000 [Commission Communication on the Precautionary Principle](#) is also an important concept in the EU's approach. Key elements in this approach were the establishment of a framework laying down the general principles and requirements of EU food law, the establishment of the European Food Safety Authority (EFSA) which is an independent body providing scientific advice to the legislators, the development of specific food and feed safety legislation and the creation of a framework for harmonized food controls. The regulations on general food law, food and feed controls, food and feed hygiene are the framework regulations for the EU's food safety system. Revisions of existing EU food regulations or new regulations all implement the principles contained in the framework regulations. Information on the EU's food safety approach is available on our website at <http://useu.usmission.gov/agri/foodsafety.html>.

For ethical issues, the Commission has given a mandate to the "European Group on Ethics" (EGE) to provide advice on ethical questions relating to sciences and new technologies. EGE delivers opinions on the ethical implications of modern developments in agriculture technologies. Its mandate is renewed every four years.

EU political structures include the permanent bureaucracy of the Commission, the Council of Member State representatives, and the European Parliament. All are involved in creating and passing legislation. For more information on how the EU works, see our website at <http://useu.usmission.gov/agri/institutions.html> and the website of the European Commission at http://europa.eu/index_en.htm. It is the task of the European Food Safety Agency (<http://www.efsa.europa.eu>) to provide scientific advice to the legislators on matters related to food safety.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by European Commission officials. The European Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

Exporters should be aware that there may be some variation among Member States in applying EU harmonized legislation. This may result from the lack of harmonized guidelines for the enforcement of rules; it may be due to variations in the transitional period needed to adjust to EU rules; there may be temporary waivers or exemptions – usually called derogations; in certain cases there may be room for interpretation of EU harmonized legislation; certain

aspects which are not regulated in detail at EU level may be handled differently in different Member States, e.g. acceptability of stick-on labels varies among Member States. Also, there is a wide variation in inspection fees, in registration fees and in the time required to evaluate dossiers on products used in the course of the food production process.

Up to date information on EU food import rules as well as general information on EU import duties and quotas can be found on our website at <http://useu.usmission.gov/agri/usda.html>. This website also links to additional sources of useful information.

AS A REMINDER: Imports of red meat, meat products, farmed and wild game meat, ratites, milk and milk products, seafood, bovine embryos an semen, porcine and equine semen, gelatin and animal casings to the EU from the U.S. may only originate from EU approved U.S. establishments.

Section II. Labeling Requirements:

SECTION II. LABELING REQUIREMENTS

<http://useu.usmission.gov/agri/label.html>

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements.

General provisions on the labeling, presentation and advertising of pre-packaged foodstuffs marketed in the EU are laid down in [European Parliament and Council Directive 2000/13/EC](#). It applies not only to foodstuffs intended for sale to the ultimate consumer but also for supply to restaurants, hospitals and other mass caterers. Section VII covers labeling requirements for specific products, including genetically modified and novel foods.

Compulsory Information:

The compulsory information must appear on the pre-packaging or on a label attached to it. The information must be marked in such a way that it is easily visible, clearly legible and indelible.

- The name under which the product is sold.

- The list of ingredients, in descending order of weight. Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, certain food colorings, aspartame and polyols, quinine and caffeine, phytosterols and phyostanols and licorice.

- Allergens: Annex IIIa to Directive 2000/13/EC lists the groups of potential allergenic ingredients which must be indicated on food labels: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products (including lactose), nuts and nut products, sesame seeds, lupin and products thereof, mollusks and products thereof and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages. [GAIN report E36066](#) lists the different languages that the EU member states will accept for the

purpose of allergen labeling of wine. Guidelines for the implementation of the allergen labeling rules are available on the Commission's website at http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf. These guidelines also specify in which cases derogations may be accepted: for foodstuffs for which no ingredients list is required, for sub ingredients of certain compound ingredients, for ingredients which belong to well defined categories and for substances that are not regarded as ingredients. Commission [Directive 2007/68/EC](#) (amended by [Commission Regulation 415/2009](#)) establishes a list of ingredients and substances which are permanently exempted from the mandatory allergen labeling requirement (for more information see [GAIN report E47105](#)).

- Certain ingredients may be designated by the name of the category rather than the specific name (Annex I to Directive 2000/13/EC). These include fats, oils (note that peanut oil is also subject to the new allergen rules), starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine. Directive 2001/101/EC adds meat as a category and defines the term "meat" for the labeling of pre-packed meat-based products (for more information see [GAIN report E23004](#)).
- The quantity of certain ingredients or categories of ingredients (QUID) – see below.
- The net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).
- The date of minimum durability: the shelf life is indicated by the words "Best before..." when the date includes an indication of the day, or by "Best before end of..." in other cases. The date has to be given in order of day- month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication. In the case of highly perishable foodstuffs the date consisting of the day, the month and possibly the year has to be preceded by the words "use by."
- Any special storage conditions or conditions of use.
- The name or business name and address of the manufacturer or packager, or of the seller established within the Community.
- Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.
- Instructions for use.
- The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.
- A mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU. The marking must be preceded by the letter "L", except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in un-coded form on the label.
- Treatments undergone, with specific indications for irradiated foods and deep-frozen foods (see section 7).

Note: the use of the EAN (European Article Numbering) product coding system is not regulated by EU law. However, this bar code system is commonly used in the EU to fulfill the traceability requirement, which became mandatory on

January 1, 2005 (See also [GAIN 35112](#)).

Additives

- Annex II to the labeling directive lists the categories of additives, which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectant, bulking agent, propellant gas.

- Flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of ingredients.

Quinine and Caffeine

[Commission Directive 2002/67/EC](#) requires the compulsory labeling of quinine and caffeine used in the production or preparation of foodstuffs (usually tonic waters and energy drinks). Quinine and caffeine must be mentioned in the ingredients list, preceded by the term "flavoring". Beverages containing more than 150 mg of caffeine per liter will have to be labeled with "high caffeine content" followed by the caffeine content expressed in mg/100 ml.

Phytosterols & Phytosterols

[Commission Regulation 608/2004](#) lays down labeling requirements for foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and phytosterol esters (used to reduce cholesterol levels). For labeling purposes, they must be designated respectively by the terms "plant sterols", "plant sterol esters", "plant stanols" and "plant stanol esters".

Quantitative Ingredients Declaration (QUID)

Quantitative ingredients declaration (QUID) is compulsory in the following cases:

- Where the ingredient or category of ingredients appears in the name under which the foodstuff is sold:
e.g. "15% strawberries" on strawberry ice cream - QUID for strawberries
"35% fruit" on fruit pie - QUID for total fruit content
- Where the ingredient or category of ingredients is usually associated with that name by the consumer: e.g. goulash soup - QUID for beef
- Where the ingredient or category of ingredients is emphasized on the labeling in words (e.g. "made with butter"), pictures (e.g. of a cow to emphasize dairy ingredients) or graphics (different size, color and/or style of print).
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from

similar products.

The QUID declaration must be indicated in or immediately next to the name under which the product is sold, unless a list of ingredients is voluntarily indicated on the label in which case the quantity may appear in the list. The quantity of the ingredient, expressed as a percentage, must correspond to the quantity of the ingredient(s) actually used in the preparation of the product.

The QUID requirement DOES NOT apply to constituents naturally present in foods and which have not been added as ingredients e.g. caffeine (in coffee) and vitamins and minerals (in fruit juices). QUID declarations are not needed in a number of cases, e.g. when products state the drained net weight or where an ingredient is used for purposes of flavoring. QUID declarations CANNOT replace nutrition labeling.

[Commission Directive 1999/10/EC](#) provides for exemptions from the QUID requirement:

- When the wording "with sweeteners" or "with sugar(s) and sweetener(s) accompanies the name under which a foodstuff is sold.
- When the addition of vitamins and minerals is subject to nutrition labeling.
- When foodstuffs are concentrated or dehydrated.

General guidelines have been drawn up to help Member States and industry organizations implement the principle of QUID. A copy of these guidelines can be downloaded from the European Commission's website at http://ec.europa.eu/food/fs/fl/fl02_en.pdf.

Warnings on Labels

[Commission Directive 2008/5/EC](#) establishes a list of foodstuffs that require a warning on the label:

- foodstuffs whose durability has been extended by means of packaging gases
- foodstuffs containing (a) sweetener(s)
- foodstuffs containing added sugar(s) and sweetener(s)
- foodstuffs containing aspartame
- foodstuffs containing more than 10% added polyols
- confectionery or beverages containing liquorice

As of July 20, 2010, [Regulation 1333/2008](#) (see section IV) requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129) and ponceau 4R (E124) to be labeled "may have an adverse effect on activity and attention in children". Food placed on the market or labeled before July 20, 2010, which do not comply with this provision may be marketed until their date of minimum durability or use-by-date.

Language Requirements

As a general rule, labeling has to be in a language easily understood by consumers; this is in practice the official

language(s) of the member state. As an exception to the general rule, it is also allowed to use:

- Another language provided it can easily be understood by consumers.
- Other means depicting the content (e.g. pictures).

Multi-language labeling is allowed throughout the EU.

Language labeling requirements in practice:

EU Member State	Language
Austria	
Belgium	French AND Dutch, German also recommended
Bulgaria	Bulgarian
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	British English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French or German
Malta	Maltese or English or Italian
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish
United Kingdom	British English

Stick-on Labels

EU legislation does not contain any reference to the use of stick-on labels. It is up to individual Member States whether to accept stick-on labels.

Samples

EU legislation covers all foods destined for consumption. It does not contain any specific labeling requirements or exceptions for samples. Exporters are advised to consult the member state FAIRS reports for specific information

(<http://useu.usmission.gov/agri/fairs.html>).

Labeling of Genetically Modified Foods

Section VII of this report is entirely dedicated to the regulatory review and commercialization of genetically modified foods in the EU and provides information on EU labeling requirements for genetically modified foods and their derivatives. All foods and ingredients that are produced in whole or in part from genetically modified organisms should indicate this on their labels. The same rules apply to flavors and additives. For detailed information see Section VII.

B. Medical / Health / Nutrition Claims

<http://useu.usmission.gov/agri/claims.html>

On July 1, 2007, a new regulation on nutrition and health claims entered into force. [Regulation 1924/2006](#) sets EU-wide conditions for the use of nutrition claims such as “low fat” or “high in vitamin C” and health claims such as “helps lower cholesterol”. The regulation applies to any food or drink product produced for human consumption that is marketed on the EU market. Only foods that fit a certain nutrient profile (below certain salt, sugar and/or fat levels) will be allowed to carry claims. Nutrition and health claims will only be allowed on food labels if they are included in one of the EU positive lists. Food products carrying claims must comply with the provisions of [nutritional labeling directive 90/496/EC](#). For more information see [GAIN reports E47090](#) on Regulation 1924/2006 and [E48055](#) on the authorization procedure.

The development of nutrient profiles, originally scheduled for January 2009, is being delayed until September 2009. Once the nutrient profiles, based on scientific evaluations by the European Food Safety Authority (EFSA), have been set, there will be another two-year period before the nutrient profiles begin to apply to allow food operators time to comply with the new rules. Nutrition claims can fail one criterion, i.e. if only one nutrient (salt, sugar or fat) exceeds the limit of the profile, a claim can still be made provided the high level of that particular nutrient is clearly marked on the label. For example, a yogurt can make a low-fat claim even if it has a high sugar content but only if the label clearly states “high sugar content”. Health claims cannot fail any criteria.

New products on the EU market must respect the conditions for using nutrition claims set out in detail in the Annex of Regulation 1924/2006. Products already labeled or on the market before January 2007 may remain on the market with the old labels until January 2010. From 2010, only nutrition claims included in the Annex will be allowed.

A list of well-established health function claims such as “calcium is good for your bones” will be established by January 2010, based on Member States’ lists of health claims already approved at national level. Disease risk reduction claims were previously not allowed in the EU which means that there is no transitional period for such claims. Disease risk reduction claims and claims referring to the health and development of children will require an authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. Health claims based on new scientific data will have to be submitted to EFSA for evaluation but a simplified authorization procedure has been established. [GAIN Report E48055](#) describes how application dossiers for authorization of health claims should be prepared and presented. A guidance document on how companies can apply for health claim authorizations can be downloaded from

EFSA's website at http://www.efsa.europa.eu/EFSA/ScientificPanels/NDA/efsa_locale-1178620753812_1178684448831.htm.

Trade marks and brand names that suggest health and/or nutritional benefits but do not comply with the new rules must be entirely removed from the EU market within 15 years.

Requirements Specific to Nutrition Labeling

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. "Nutrition labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fiber, sodium, vitamins and minerals present in significant amounts. Nutrition labeling rules are laid down in [Council Directive 90/496/EEC](#).

Where nutritional labeling is provided, the information to be given should consist of either group 1 or group 2 in the following order:

Group 1	Group 2
- the energy value	- the energy value
- the amount of protein, carbohydrate and fat	- the amount of protein, carbohydrate, sugar, fat, saturates, fiber and sodium

When a nutrition claim is made for sugars, saturates, fiber and sodium, the information under Group 2 must be given.

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA).

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser. Examples of the nutrition information panel can be found in a [leaflet](#) published by the EU's Food & Drink Industry Confederation (CIAA).

In October 2008, Council Directive 90/496/EEC was amended by [Commission Directive 2008/100/EC](#). Commission Directive 2008/100/EC updates the list of vitamins and minerals and their Recommended Daily Allowances (RDAs) and provides an EU definition of "fiber". The conditions for the use of nutrition claims such as "source of fiber" or "high fiber" are laid down in Regulation 1924/2006 (see nutrition and health claims).

C. Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. These include:

- genetically modified foods

- novel foods
- fortified foods
- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- beef
- wine
- spirit drinks
- olive oil
- organic foods
- cocoa and chocolate products, sugars, honey, fruit juices and similar products, preserved milk
- coffee extracts and chicory extracts, fruit jam, jellies, marmalades and chestnut puree
- fresh fruits and vegetables
- meat, poultry, eggs, dairy products, spreadable fats
- seafood

More details on above products can be found in Section VII.

D. Country of Origin Labeling

In the EU, country of origin labeling is mandatory for beef and veal, fruit and vegetables, eggs, poultry meat, wine, honey, olive oil, aquaculture products and organic products (as of 2010). For other products, the indication of the place of origin or provenance is mandatory only if the omission of such information might mislead the consumer.

Proposal: On January 30, 2008, the European presented a proposal to revise the EU's general food labeling requirements. New requirements would include the mandatory declaration of nutrition information on the front label of pre-packaged foods, a minimum font size of 3 mm for printing mandatory information and an ingredients list on the label of alcopops. For more information on the labeling proposal see [GAIN Report E48020](#).

Section III. Packaging and Container Regulations:

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

<http://useu.usmission.gov/agri/packaging.html>

A. Size & Content

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in [Council Directive 76/211/EEC](#), as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:

- nominal quantity greater than 1000 g or 100 cl: at least 6 mm high
- greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm
- greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm
- less than 50 g/2 cl: 2 mm. The quantity must be followed by the unit of measurement.

[Directive 2007/45/EC](#) abolishes regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, coffee and white sugar. Member States in which mandatory nominal quantities are prescribed for milk, butter, dried pasta and coffee may maintain their restrictive rules until October 2012. The rules for white sugar may be maintained until October 2013. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC.

B. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials (Council Directive 94/62/EC). To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. A well-known and widely used recycling program is the German “green dot” system. More information can be found on the Packaging Recovery Organization Europe website which provides easy access to all Green Dot systems in Europe (www.pro-e.org).

C. Materials in Contact with Foodstuffs

[European Parliament and Council Regulation 1935/2004](#) specifies the main requirements for materials that come into contact with foodstuffs. It also sets out labeling & traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority. Additional requirements will be proposed in specific measures and will include positive lists of authorized substances and/or materials. Annex I to regulation 1935/2004 lists the group of materials for which specific measures may be adopted. To date, [specific directives](#) have been developed for plastics, regenerated cellulose film, ceramics. In the case of ceramics, migration limits have been established for two of their constituents, namely lead and cadmium. Materials must bear an indication "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

[Commission Regulation 450/2009](#) sets out definitions and authorization procedures for the use of active and intelligent materials and articles intended to come into contact with food.

[Commission Regulation 2023/2006](#) lays down rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food listed in annex I to Regulation 1935/2004.

Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain substances not listed in one of the specific directives. They may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives for reasons of public health. A summary of national legislation can be downloaded from the European Commission website at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf.

Section IV. Food Additives Regulations:

SECTION IV. FOOD ADDITIVE REGULATIONS

<http://useu.usmission.gov/agri/additive.html>

In December 2008, the proposal for a legislative “Package on food Improvement Agents” was adopted. The package includes four new regulations: [Regulation 1331/2008](#) establishing a common authorization procedure for food additives, food enzymes and food flavorings, [Regulation 1332/2008 on food enzymes](#), [Regulation 1333/2008 on food additives](#) and [Regulation 1334/2008 on flavorings](#).

Additives

New [Regulation 1333/2008 on food additives](#) brings the current miscellaneous additives directive and the directives on colors and sweeteners into one regulation and will apply as of January 20, 2010 (except for the transitional provisions). It provides for the establishment of an EU positive list, conditions of use and rules on the of additives sold as such.

Additives that are permitted under the existing directives will be entered in the EU positive list of authorized additives (Annex II to Regulation 1333/2008) after a review of their compliance with the new provisions. This review should be completed by January 2011. Until the completion of the review, the use of food additives permitted under the current directives will continue to be permitted. An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

For an overview of the rules in force until the new regulation becomes applicable see the [2008 FAIRS report](#) (GAIN report E48078).

Flavorings

Current rules

[Council Regulation 2232/96](#) sets out the basic rules for the use of flavoring substances in or on foodstuffs. It also establishes a procedure for the establishment of a Community list of flavoring substances.

In an initial step to harmonize the use of flavorings in the EU, the European Commission compiled a [register of all flavoring substances](#) (last amended by [Commission Decision 2009/163/EC](#)) authorized in the different EU member states. Substances that are subject to restrictive or prohibitive measures in certain member states have been marked. This register is subject to an evaluation program in order to establish a positive EU list of authorized substances (adoption expected by the end of 2010).

Smoke Flavorings: [Regulation 2065/2003](#) on smoke flavorings establishes a Community procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods.

New rules

[Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties updates the current legislation and sets specific rules for the use of the term “natural”. The EU positive list of authorized flavorings has to be adopted at the latest by December 31, 2010. The new rules will apply as of January 20, 2011.

Enzymes

Regulation 1332/2008 on food enzymes introduces harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Until the adoption of an EU positive list of authorized enzymes, the existing national provisions on the marketing of food enzymes will continue to apply.

Processing Aids

A list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council [Directive 2009/32/EC](#).

Section V. Pesticides and Other Contaminants:

SECTION V. PESTICIDES AND OTHER CONTAMINANTS

Pesticides

<http://useu.usmission.gov/agri/pesticides.html>

The legislation on pesticides and contaminants is partially harmonized in the EU. Enforcement of both EU and remaining Member State rules is done at the Member State level.

The marketing and use of [plant protection products](#) is regulated by [Council Directive 91/414/EEC](#). This Directive provides for the establishment of an EU positive list of active substances. Active substances are being reviewed under

this Directive and may only be used in plant protection products when they are included in the positive list. Only products containing substances included in the positive list may be authorized for use in the EU. The currently ongoing legislative initiatives in the area of pesticides are resulting in a drastic reduction of the number of active substances and maximum residue levels (MRLs) are being harmonized throughout the EU.

Proposal: A European Commission [proposal](#) to replace the current pesticides directive is still going to the legislative procedure with formal adoption by the Council expected at the end of this year. When adopted, the new pesticides regulation will establish new rules for the authorization of Plant Protection Products and replace current Directive 91/414/EEC. The main aim of the proposal is to facilitate the current approval and authorization procedures and to increase harmonization while maintaining a high level of protection for humans, animals and the environment.

On September 1, 2008, framework [Regulation 396/2005](#) on maximum levels of pesticides in or on food and feed of plant and animal origin became fully applicable replacing old Directives 86/362/EEC, 86/363/EEC and 90/642/EEC.

Regulation 396/2005 becomes fully applicable six months after publication of the first four Annexes in the Official Journal. Annex I was published in 2006; Annexes II, III and IV were published at the beginning of March 2008 which means that Regulation 396/2005 will become fully applicable at the beginning of September 2008.

Annex I simply lists the **commodities** to which MRLs apply.

Annex II contains **existing MRLs** that were already harmonized at EU level and will replace the EU's current MRL Directives. They may be higher than the default limit.

Annex III is the list of the so-called EU temporary MRLs. It is the result of the harmonization process as it lists pesticides for which, before September 1, 2008, MRLs were only set at national level. It specifies MRLs for 471 pesticides.

Annex IV contains the substances for which **no MRLs are required** (exempt from tolerance products).

Annex V will contain the list of pesticides for which a default limit other than 0,01 mg/kg will apply. This Annex has not been published yet.

Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients. **Annex VI** will contain the list of conversion factors of MRLs for processed commodities. This Annex has not been published yet.

Annex VII contains a list of pesticides used as fumigants for which the Member States are allowed to apply special derogations before the products are placed on the market.

If a pesticide is not included in any of the above mentioned Annexes the default MRL of 0,001 mg/kg applies. However, exporters can obtain an "import tolerance" even for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority (EFSA) before being forwarded to the Commission for consideration. Information on import tolerances can be obtained from http://www.pesticides.gov.uk/applicant_guide.asp?id=1239

When fully implemented, all MRLs, including import tolerances, will apply EU wide, removing possible trade problems that were the result of the previous/current situation whereby Member States can set their own national MRLs in the absence of harmonized EU MRLs.

Harmonized sampling plans have been developed for the official control of residues ([Commission Directive 2002/63/EC](#)).

Contaminants

<http://useu.usmission.gov/agri/contaminants.html>

Maximum Levels

EU wide harmonized maximum levels for contaminants are set in the Annex of [Commission Regulation 1881/2006](#). The Annex to Regulation 1881/2006 includes maximum levels for:

- nitrates in lettuce, spinach and infant food (section 1)
- mycotoxins (section 2):
 - aflatoxins in nuts, dried fruit, cereals, maize, spices, milk and infant food
 - ochratoxin A in cereals, cereal products, dried vine fruit and infant food
 - patulin in apple juice, apple juice ingredients and infant food
 - deoxynivalenol in cereals, cereal products and infant food
 - zearalenone in cereals, cereal products and infant food
 - fumonisins in maize and maize based products
 - T-2 and HT-2 toxin in cereals and cereal products
- heavy metals (section 3):
 - lead, cadmium, mercury in meat, fish, vegetables and fruit, and food supplements
 - tin in canned foods, beverages and baby foods
- 3-MCPD in vegetable protein and soy sauce (section 4)
- dioxin and PCBs in meat, fish, fish liver and derived products, milk, eggs and oils & fats (section 5)
- polycyclic aromatic hydrocarbons (PAH) in oils & fats, infant foods, meat and fish (section 6)

Commission Decision 2006/504/EC sets special conditions for the import of foodstuffs from certain third countries due to contamination risks by aflatoxins. An update of the Commission's "[Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins](#)" was published in March 2009. Commission Decision 2007/563/EC, an amendment to Decision 2006/504/EC, sets special conditions for the import of U.S. almonds into the EU. The decision applies to almonds in shell or shelled, roasted almonds, and mixtures of nuts or dried fruits containing almonds, and foodstuffs containing a significant amount of almonds (at least 10 percent). Official Member States controls are carried out on approximately 5 percent of consignments of foodstuffs which are covered by the "Voluntary Aflatoxin Sampling Plan" (VASP) and to each consignment of foodstuffs not covered by the VASP. More information is available on the [Almond Board of California's website](#).

Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis:

- Nitrates: [Commission Regulation 1882/2006](#)
- Mycotoxins: [Commission Regulation 401/2006](#)
- Dioxins: [Commission Regulation 1883/2006](#)
- Heavy metals: [Commission Regulation 333/2007](#)

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed separately in [Council Directive 96/23/EC](#). This directive includes the monitoring of the above-mentioned pesticide residues but includes also the monitoring of residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in [Council Directive 96/22/EEC](#) (amended by [Directive 2008/97/EC](#)).

Section VI. Other Regulations and Requirements:

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The weekly reports of the notifications under the rapid alert are available on the European Commission's website (http://ec.europa.eu/food/food/rapidalert/index_en.htm). The information published on the website is limited to the notifying country, the reason for notifying and the country of origin. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses.

Specific detailed inspection requirements exist for animal products ([Directive 97/78/EC](#)). Products of animal origin must be presented at a Community border inspection post and submitted to an import control following prior notification of the shipment. The list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and the list of animals and animal products that are subject to controls at border inspection posts can be accessed through our website at <http://useu.usmission.gov/agri/borderposts.html>. [Commission Decision 207/275/EC](#) sets out import conditions for products of animal origin that are subject to veterinary checks at border inspection posts, including certain composite products and lists those composite products that are not subject to veterinary checks.

[Regulation 854/2004](#) lays down specific rules for the organization of official controls on products of animal origin. [Regulation 882/2004](#) lays down general rules for the performance of official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. [Commission Regulation 669/2009](#) implements Regulation 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described on <http://useu.usmission.gov/agri/certification.html>.

Inspection fees for non-animal origin products differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods. The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Health and Consumer Protection Directorate. Importers of organic products are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

http://useu.usmission.gov/agri/Certification_Guide.html

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available in [GAIN report E48108](#). An update of this report will be published in September 2009. Detailed information on certification is also available on our website at http://useu.usmission.gov/agri/Certification_Guide.html.

Section VII. Other Specific Standards:

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods (GMOs)

<http://useu.usmission.gov/agri/GMOs.html>

Labeling regulations for GM food products are established by [Regulation 1829/2003](#) (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

All food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be labeled even if they no longer contain detectable traces of GMOs. The allowable adventitious presence level for EU-approved varieties of GMOs is set at 0.9 percent. Above this level all products must be labeled. The transitional provision that allowed an adventitious presence level of 0.5 percent for GM varieties that received a positive EU risk assessment but are not yet formally approved expired in April 2007.

The wording to be used on GM food labels is as follows:

- Where the food consists of more than one ingredient, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled “contains [name of ingredient] produced from genetically modified [name of organism]”. Example: a biscuit containing soy flour derived from GM-soy must be labeled “contains soy flour from genetically modified soy”.
- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words “contains genetically modified [name of organism]” or “contains [name of ingredient] produced from genetically modified [name of organism]” must be used. Example: for vegetable oils containing rapeseed oil produced from genetically modified rapeseed, the reference “contains rapeseed oil from genetically modified rapeseed” must appear in the list of ingredients.

The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

- Where there is no list on ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling. Example 1: “a spirit containing caramel produced from genetically modified corn”.

Example 2: “genetically modified sweet corn”.

For more information see the 2009 Annual Agricultural Biotechnology Report (GAIN report E49052).

B. Novel Foods

(<http://useu.usmission.gov/agri/novelfood.html>)

The [Novel Food Regulation 258/97](#) lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from or containing or consisting of GMOs. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The new regulations on GM food provide for a separate regime to deal with the authorization and traceability of novel foods and novel food ingredients that consist of or contain or are derived from GMOs. Pre-market approval of non-GM novel foods will continue under European Parliament and Council Regulation 258/97. Non-GM categories of novel foods consist of food and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of, or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or
- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

The full list of novel food applications and authorizations/rejections/withdrawals is available from

http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf.

Proposal: On January 14, 2008, the European Commission presented a proposal to revise the current rules on novel foods. The proposal covers foods that have been produced using new techniques (such as animal cloning) and new technologies (such as nanotechnology) and foods which have a safe history of use in third countries (such as noni juice). Only foods included in the "Community list of novel foods" will be allowed on the EU market. For detailed information on the Novel Foods proposal see [GAIN Report E48014](#) and [GAIN Report E48149](#).

C. Fortified Foods

(<http://useu.usmission.gov/agri/foodsupplements.html>)

[Regulation 1925/2006](#) establishes an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods

and sets criteria for setting maximum and minimum levels. The Commission proposal setting minimum and maximum levels, originally scheduled for January 2009, is being delayed until the end of 2009. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. However, Member States may under certain conditions provide for a temporary derogation (until January 19, 2014) for vitamins and minerals not included in the annexes. Foods not complying with the new rules may be marketed until December 31, 2009, if they were put on the market or labeled before July 1, 2007 (date of entry into force of the regulation).

D. Dietetic or Special Use Foods

(<http://useu.usmission.gov/agri/partnutr.html>)

New framework [Directive 2009/39/EC](#) consolidates Directive 89/398/EEC and all its amendments into a single text and lays down rules for foodstuffs intended for particular nutritional uses. These are foodstuffs, which due to their special composition or manufacturing process, can clearly be distinguished from foodstuffs for normal consumption. [Commission Directive 2001/15/EC](#) lists the chemical substances in each category of nutritional substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions including compositional and hygiene requirements, provisions regarding the quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

- [Commission Directive 2006/125/EC](#) on processed cereal-based foods and baby foods for infants and young children.
- [Commission Directive 96/8/EC](#) on foods intended for use in energy-restricted diets for weight reduction.
- [Commission Directive 2006/141/EC](#) on infant formula and follow-on formula, amended by [Commission Regulation 1243/2008](#) as regards compositional requirements for certain infant formulae.
- [Commission Directive 1999/21/EC](#) on dietary foods for special medical purposes.

[Commission Regulation 41/2009](#) lays down new EU harmonized rules for the composition and labeling of foodstuffs suitable for people who are intolerant to gluten. This regulation, applicable as of January 1, 2012, sets conditions for the use of the terms “very low gluten” and “gluten-free”. For more information see [GAIN report E49009 “New EU labeling rules for “gluten free” foods”](#).

To take advantage of technological developments, the Commission may authorize the marketing of products, which do not comply with the requirements of the specific directives for a two-year period.

Specific directives on foods and beverages for sports people or on foods intended for diabetics are still subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold. A list of competent Member State authorities can be downloaded at http://ec.europa.eu/food/food/labellingnutrition/nutritional/list_auth_art9_en.pdf.

E. Single Common Market Organization (CMO)

[Council Regulation 1234/2007](#) establishes a single common market organization (CMO) for all agricultural products and replaces 21 existing specific CMOs for different agricultural sectors. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine.

Animal Products

Veal

Labeling requirements for meat of bovine animals aged 12 months or less are laid down in Annex XIa to Council Regulation 1234/2007. Bovine animals aged less than 12 months are classified in two categories: 1) bovine animals aged 8 months or less and 2) bovine animals aged more than 8 months but less than 12 months. Regulation 361/2008 lists the different sales descriptions for the two categories. [Commission Regulation 566/2008](#) lays down detailed rules (compulsory information on labels and trade with third countries) for the marketing of the meat of bovine animals aged 12 months or less.

Egg Marking

[Commission Regulation 589/2008](#) lays down detailed rules for implementing Council Regulation 1234/2007 as regards marketing standards for eggs. The U.S. currently only exports shell eggs to the EU for breaking and further processing in food processing facilities. Such eggs are graded as "class B" eggs under EU standards. According to EU interpretation of Article 30 of Regulation 589/2008, eggs imported from third countries, including eggs for processing, must be clearly and legibly marked in the country of origin in accordance with the ISO 3166 country code. In practice, this means that each egg individually has to be marked "USA". [Commission Regulation 598/2008](#) provides, under strict conditions, for an exemption from the marking requirement. [Commission Regulation 617/2008](#) lays down rules for the marking of eggs for hatching.

Fruit and Vegetables

(<http://useu.usmission.gov/agri/Fruit-Veg.html>)

Starting July 1, 2009, [Commission Regulation 1221/2008](#) (which will be integrated into the single CMO) repeals existing marketing standards for 26 products: apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, Brussels sprouts, cabbage, carrots, cauliflowers, celery, courgettes (zucchini), cucumbers, cultivated mushrooms, garlic, hazelnuts in shell, headed cabbage, leeks, melons, onions, peas, plums, ribbed celery, spinach, walnuts in shell, water melons and chicory. Regulation 1221/2008 provides for a general marketing standard for all fresh fruits and vegetables except for 10 types of fruit and vegetables for which a specific marketing standard remains in place: apples, citrus fruit, kiwi fruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes. The specific marketing standards are set out in Part B of Annex I to Regulation 1221/2008. Fruits and vegetables not covered by a

specific marketing standard must comply with the general marketing standard. Marketing standards apply at all marketing stages including import. For more information see [GAIN report E49013](#).

Fresh fruits, vegetables and nuts are subject to phytosanitary controls and are checked for compliance with the quality standards and labeling requirements. A conformity certificate or a certificate of industrial use, to be obtained by the importer at the point of entry, is required for all shipments of fresh produce.

F. Wine, Beer and Other Alcoholic Beverages

(<http://useu.usmission.gov/agri/wine.html>)

[Council Regulation 479/2008](#) reorganizes the way the EU wine market is managed. It establishes general rules, applicable as of August 1, 2009, on oenological practices, designations of origin and labeling.. Measures for the adoption of Regulation 479/2008 were published on July 24, 2009 (Official Journal L 193).

[Commission Regulation 606/2009](#) lays down detailed rules for implementing Regulation 479/2008 as regards permitted oenological practices. Annex I A sets out the oenological practices authorized in the EU and the conditions for their use. For experimental purposes, Member States may authorize the use of certain oenological practices not provided for in the relevant EU regulations for a maximum of three years. Annex I B sets out the maximum allowed sulphur dioxide contents: 150 mg per liter for red wines, 200 mg per liter for white and rosé wines.

[Commission Regulation 607/2009](#) lays down detailed rules for implementing:

- Chapter IV of Title III of Regulation 479/2009 relating to protected designations of origin and geographical indications
- Chapter V of Title III of Regulation 479/2008 relating to traditional terms
- Chapter VI of Title III of Regulation 479/2008 relating to the labeling and presentation of wine sector products.

Chapter II of Regulation 607/2009 establishes the application procedure for a designation of origin or a geographical indication. Designation of origin or geographical indications which have been accepted will be entered in a “Register of protected designations of origin and protected geographical indications” maintained by the European Commission. The register will be made available electronically.

Annex XII to Regulation 607/2009 establishes a list of protected traditional terms. The use of expressions such as “style”, “type”, “method”, “as produced in”, “imitation”, “flavor”, “like” or similar, accompanied by a traditional terms included in Annex XII is not allowed. Third countries may use traditional terms not listed in Annex XII.

Chapter IV of Regulation 607/2009 sets out rules for the indication of compulsory and optional information on wine labels. The mandatory information must appear in the same field of vision on the container, in such a way that all the information (except the lot number) is readable without having to turn the container. The mandatory information must be clearly distinguishable from surrounding text or graphics. Ingredients which may trigger an allergic reaction ([see Annex IIIa to labeling directive 200/13/EC](#)) must be indicated on the label preceded by the word “contains”. For the indication of sulphites, the following terms may be used: “sulphites”, “sulfités”, “sulphur dioxide” or “sulfur dioxide”. The indication of sulphites may be accompanied by the pictogram included in Annex X to Regulation 607/2009. The

indication of the wine grape variety on the label is optional. For third country wines, the wine grape variety must be included in at least one of the lists established by the “international Organization of Vine and Wine (OIV), the “Union for the Protection of Plant Varieties (UPOV)” or the “International Board for Plant Genetic Resources (IBPGR)”. Terms such as “barrel matured”, “barrel aged” (listed in Annex XVI to Regulation 607/2009) may not be used on wines produced with the aid of oak chips.

Framework Regulation 479/22008 provided for the implementing rules to enter into force on August 1, 2009. As the implementing rules were only published on July 24, 2009, a transitional period is provided in order to ease the transition to the new requirements. Wines placed on the market or labeled before December 31, 2010, that comply with the provisions applicable before August 1, 2009 (rules laid down in [Council Regulation 1493/1999](#)), may be marketed until stocks are exhausted.

Specific rules for organic wines have not yet been adopted. Terms referring to the organic production of grapes are established by [Council Regulation 834/2007](#).

In March 2006, the U.S. and the EU and the U.S. signed the [“Agreement between the United States and the European Community on Trade in Wine”](#). This Agreement is the first phase and addresses a number of issues, such as labeling and certification. Other important issues such as geographical indications will be addressed in a second phase of the negotiations. The Agreement covers wine with an actual alcohol content of not less than 7% and not more than 22%. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified in Annex III(a) to the Agreement. More information on the simplified EU import certificate form can be obtained from the Alcohol and Tobacco Tax and Trade Bureau at http://www.ttb.gov/industry_circulars/archives/2007/07-02.html. The Agreement’s “Protocol on Wine Labeling” sets conditions for the use of optional particulars on wine labels. Information on the US-EU Wine Agreement can also be obtained from the U.S. Dept. of the Treasury - Alcohol and Tobacco Tax and Trade Bureau (http://www.ttb.gov/agreements/us_ec_wine_agreement.shtml).

[European Parliament and Council Regulation 110/2008](#) was published in February 2008 and entered into force on May 20, 2008. This new regulation lays down general rules on the definition, description and presentation of spirit drinks. Spirit drinks not meeting the requirements of the new regulation may continue to be marketed until May 20, 2009. There is no Community legislation for beer, although some member states have adopted national provisions to make the list of ingredients compulsory.

All alcoholic beverages containing sulphur dioxide and sulphites at concentrations of more than 10 mg/liter must be labeled “contains sulphites” or “contains sulphur dioxide”. Replacing the word “sulphites” by “SO₂” or the E-number (E220) is not allowed. The list of authorized languages for allergen labeling can be consulted in [GAIN report E36066](#).

G. Organic Foods

(<http://useu.usmission.gov/agri/organic.html>)

[Council Regulation 834/2007](#) lays down a new legal framework for organic production and the labeling of organic products. Title IV of this new regulation lays down general rules for the labeling of organic products; Title VI covers trade with third countries. [Commission Regulation 889/2008](#) lays down detailed rules for the implementation of

Regulation 834/2007 with regard to production, labeling and control. The use of an EU organic logo will become mandatory for products produced in the EU but will be optional for organic products from third countries. However, due to “technical” problems with the design, the use of a new EU organic logo will be delayed until July 2010. Regulation 834/2007 entered into force on January 1, 2009 and repeals Council Regulation 2092/91. The new EU rules on organic food labeling are explained in [GAIN report E48106](#).

[Commission Regulation 1235/2008](#) lays down rules for the implementation Regulation 834/2007 as regards the arrangements for imports of organic products from third countries. In order to export organic products to the EU, third countries must prove that their production standards are equivalent to the EU standards. For third countries currently not included in the EU’s equivalency list, such as the U.S., the Commission will compile a list of recognized control bodies and control authorities. To be included in the EU list, U.S. control bodies/authorities must submit a technical dossier. The Commission will only consider complete dossiers submitted before October 31, 2011. To avoid trade disruptions, Regulation 1235/2008 establishes transitional rules allowing Member States, until January 1, 2013, to continue to grant authorizations to importers of U.S. organic products on a case-by-case basis. Authorizations will expire at the latest 24 months after the publication of the first list of control bodies/authorities. Shipments of organic products must be accompanied by the model certificate established by Regulation 1235/2008.

H. Vertical Legislation (Breakfast Directives)

(<http://useu.usmission.gov/agri/vertic.html>)

Vertical legislation on the manufacture and marketing of specific products has been developed for sugars, cocoa and chocolate products, honey, fruit juices and similar products, preserved milk, coffee extracts and chicory extracts and fruit jams and similar products.

I. Beef Labeling

(<http://useu.usmission.gov/agri/label>)

A compulsory beef labeling scheme has been in place since September 2000. Full implementation of the beef labeling scheme went into effect on January 1, 2002. (Regulations [1760/2000](#) and [1825/2000](#)). Under this scheme, labels for all bovine meat must indicate the following information:

“Born in: name of third country”
“Reared in: name of third country or third countries”
For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as “Origin: name of third country”
A reference number ensuring the link between the meat and the animal or animals
“Slaughtered in: third country / approval number of slaughterhouse”
“Cutting in: third country / approval number of cutting plant”
A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day

J. Health & Identification Marks

The EU's "Food Hygiene Package" introduced new rules concerning the application of health and identification marks. Chapter III of [European Parliament and Council Regulation 854/2004](#) lays down rules for applying a health mark to fresh meat. More information on the EU health mark is available on USDA's Food Safety Inspection Service's website at

http://www.fsis.usda.gov/regulations_&_policies/European_Union_Requirements/index.asp. Annex II to [European Parliament and Council Regulation 853/2004](#) lays down rules for applying an identification mark to products of animal origin. Linear presentation of the required information is allowed only for imports from EU-approved establishment in third countries. More information on the EU's identification mark is available on USDA's Agricultural Marketing Service's website at <http://www.ams.usda.gov/AMsv1.0/getfile?dDocName=STELPRDC5061042>.

K. Frozen Foodstuffs

(<http://useu.usmission.gov/agri/frozen.html>)

[Council Directive 89/108/EEC](#) sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication "quick-frozen", the date of minimum shelf life, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, batch identification and a clear indication of the type "do not re-freeze after defrosting".

L. Irradiated Foodstuffs

(<http://useu.usmission.gov/agri/irradiation.html>)

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval.

[Framework Directive 1999/2/EC](#) outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods must be labeled "irradiated" or "treated with ionizing radiation".

[Implementing Directive 1999/3/EC](#) establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings". Until the positive list is expanded, the national authorizations listed on our website continue to apply.

M. Seafood

(<http://useu.usmission.gov/agri/seafood2.html>)

[Council Regulation 2406/96](#) lays down common marketing standards for certain fishery products.

Fishery and aquaculture products offered for retail sale in the EU must be properly labeled providing the following information:

- Commercial name of the species (each member state has established a list of commercial designations).
- Product method: “caught in...”, “caught in freshwater”, “farmed” or “cultivated”.
- Catch area: for products caught at sea, a reference to one of the areas listed in the annex. For products caught in freshwater, a reference to the country of origin; for farmed products, a reference to the country in which the product undergoes the final development stage. Operators may indicate a more precise catch area. To improve the traceability and control at all marketing stages - from the ship to the shop - the information concerning the commercial designation, the production method and the catch area for all fishery and aquaculture products must be provided either on the label, on the packaging or by means of a commercial document accompanying the goods (e.g. the invoice).

Detailed information on exporting U.S. seafood to the EU is available in the 2009 update of the “How to export seafood to the European Union” guide which can be downloaded from

<http://useu.usmission.gov/agri/private/How%20to%20export%20seafood%202009.pdf>.

N. Pet Food

(<http://useu.usmission.gov/agri/petfood.html>)

The current EU rules (detailed information available on our website) which are scattered over a series of directives and regulations have a direct impact on the production and marketing of pet food. In June 2009, a new framework regulation was adopted which will replace the existing rules and implement labeling and marketing rules in a more uniform way. Labeling rules will be similar to those for food for human consumption, i.e. ingredients must be listed in descending order of weight. If the presence of a certain feed material is emphasized, its exact percentage by weight must be indicated. The new regulation has not been published yet in the Official Journal but will probably enter into force in the beginning of 2010.

Section VIII. Copyright and/or Trademark Laws:

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

Trademarks

[Council Regulation 207/2009](#) lays down rules for the registration of Community trademarks. It creates a single, unitary registration system covering the whole Community.

In practice, a Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to the fees set out in Commission Regulation 2869/95, or at a national industrial property office in a Member State of the European Union.

On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

The Community Trademark did not replace the existing trademark laws of the member states but co-exists alongside national trademarks. [Directive 2008/95/EC](#) approximates the laws of the Member States relating to trade marks.

Protected Geographical Indications

(<http://useu.usmission.gov/agri/GI.html>)

[Council Regulation 510/2006](#) lays down the rules on the protection of designation of origin and geographical indications for agricultural products intended for human consumption (except wine and spirit drinks which are covered by separate legislation). [Commission Regulation 1898/2006](#) lays down detailed rules for the implementation of Regulation 510/2006. Under these regulations, third country operators can submit registration applications directly to the Commission and object directly to new registrations. Guidelines for the registration of GIs by third country producers have been published on the Commission's website at

http://ec.europa.eu/agriculture/foodqual/protec/thirdcountries/proced_en.pdf. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's [online "DOOR" \(Database of Origin and Registration\) database](#).

Section IX. Import Procedures:

SECTION IX. IMPORT PROCEDURES

[Council Regulation 2913/92](#) establishes the Community Customs Code. [Commission Regulation 2454/93](#) lays down provisions for the implementation of the Code. The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the Member States of the European Union form a customs union which means that all the Member States apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one Member State, it can move freely throughout the EU.

[Regulation 648/2005](#), a "security amendment" to Regulation 2913/92, introduces a number of measures to tighten security for goods crossing international borders. The provisions to implement the security amendment to the Customs Code are established by [Council Regulation 1875/2006](#). Since July 1, 2009, it is mandatory for traders to provide customs authorities with advance information on goods imported into the EU. For more information see DG Taxation & Customs Union website:

http://ec.europa.eu/taxation_customs/customs/policy_issues/customs_security/security_initiatives/index_en.htm.

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings, the two following digits represent the CN subheadings. The EU's on-line customs database can be consulted to look up commodity codes and relevant import duties (http://ec.europa.eu/taxation_customs/dds/tarhome_en.htm).

It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI is legally binding in all the member states. Information on how to obtain a BTI can be downloaded from the European Commission's Taxation & Custom's website at

http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/classification_goods/index_en.htm. A list of customs authorities can be found at http://ec.europa.eu/taxation_customs/common/links/customs/index_en.htm. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

- import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces)
- additional duties on flour and sugar (processed products)
- entry price (fruit and vegetables)
- environmental taxes - not harmonized
- inspection fees - not harmonized
- Value Added Tax (VAT) - not harmonized
- excise duties (alcohol and tobacco) - not harmonized

A list of VAT rates applicable in the different Member States can be found on the Internet at http://ec.europa.eu/taxation_customs/taxation/vat/consumers/vat_rates/index_en.htm.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://ec.europa.eu/taxation_customs/taxation/excise_duties/alcoholic_beverages/rates/index_en.htm and http://ec.europa.eu/comm/taxation_customs/taxation/excise_duties/tobacco_products/rates/index_en.htm respectively.

Other customs procedures described in detail in the Code include entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market. The Code also provides for a two-stage right of appeal lodged in the Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

Appendix I. Government Regulatory Agency Contacts:

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

Commission of the European Communities

Rue de la Loi 200
1049 Brussels
Belgium
Tel: (32-2) 299 11 11

Office for Harmonization in the Internal Market

Avenida de Aguilera, 20
03080 Alicante
Spain
Tel. (34-96) 513 92 43
Fax. (34-96) 513 91 73

European Union - Delegation of the European Commission to the United States

2300 M Street
NW, Washington, DC 20037
Tel: (202) 862-9500
Fax: (202) 429-1766

United States Mission to the European Union

Office of Agricultural Affairs
Organization chart: <http://useu.usmission.gov/agri/staff.html>
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)508-2760
Fax: (32) (2) 511-0918
e-mail: AgUSEUBrussels@fas.usda.gov

Other FAS Offices in the European Union <http://useu.usmission.gov/agri/FAS-in-EU-27.html>

USDA/FDA contacts for certification of animal products <http://useu.usmission.gov/agri/certification.html>

USDA/FDA contacts for U.S. export requirements and documentation
http://www.fas.usda.gov/agx/ship_doc_req/food_ag_us_req.asp

Appendix II. Other Import Specialist Contacts: APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

Please see [Member States FAIRS reports](#).

Author Defined:

APPENDIX III. HOW TO OBTAIN LEGISLATION

<http://useu.usmission.gov/agri/legis.html>

The Official Journal (<http://eur-lex.europa.eu/JOIndex.do?ihmlang=en>)

The Official Journal is the EU equivalent to the U.S. Government's "Federal Register". The L (Legislation) and C (Information and Notices) series of the Official Journal are published daily in all the official languages of the EU.

Legislation in force (<http://eur-lex.europa.eu/en/legis/index.htm>)

The texts are arranged under twenty main chapter headings. Legislation relating to agriculture, biotechnology, organic farming, foodstuffs, etc. can be found under heading 03 "Agriculture" and heading 15 "Environment, Consumers and Health Protection". On this site you can find the initial legislation and all the amendments as published in the Official Journal. The Directory also gives access to **consolidated texts**, which have no legal value but which integrate a basic instrument of Community legislation with its subsequent amendments and corrections in a single text.

APPENDIX IV. EU INITIATIVES

This report gives an overview of EU food laws currently in force. However, below follows a list of EU proposals / initiatives that may possibly affect U.S. food exports to the EU:

- Acrylamide
- Animal welfare labeling
- Eco-labeling
- Food contact materials
- Functional foods
- Geographical Indications
- Novel foods
- Nutrition labeling
- Organic food
- Pesticides
- Review of labeling rules

In May 2009, the European Commission published its "Communication on Agricultural Product Quality Policy" which outlines a number of policy options including a recast of the geographical indications legislation and identifies three main issues (information, coherence, complexity) that should be addressed in the development of a new food quality

policy. For detailed information see [GAIN report E49053 “EU Orientation Paper on a New Food Quality Policy”](#).

Please check our website (<http://useu.usmission.gov/agri/usda.html>) for updates and reports on legislative developments. You can also subscribe to our e-newsletter “What’s new on the USEU Agric Website” by sending an e-mail to Hilde.Brans@fas.usda.gov.

APPENDIX IV. WEBSITE LINKS & GUIDANCE DOCUMENTS

EUROPEAN COMMISSION:

- DG Health & Consumers: http://ec.europa.eu/dgs/health_consumer/index_en.htm
- DG Agriculture: http://ec.europa.eu/agriculture/index_en.htm
- DG Taxation & Customs Union: http://ec.europa.eu/taxation_customs/index_en.htm

EU Decision-Making Procedures:

- http://eur-lex.europa.eu/en/droit_communaire/droit_communaire.htm

European Food Safety Authority (EFSA):

- http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm

U.S. Mission to the EU:

- Foreign Agricultural Service: <http://useu.usmission.gov/agri/usda.html>
- Foreign Commercial Service: <http://www.buyusa.gov/europeanunion/>

FAIRS Reports:

- <http://useu.usmission.gov/agri/fairs.html>
- <http://gain.fas.usda.gov/Pages/Default.aspx>

GUIDANCE DOCUMENTS:

- Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins: http://ec.europa.eu/food/food/chemicalsafety/contaminants/aflatoxin_guidance0309_en.pdf
- EU general food law – implementation guidelines: http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf
- How to read a food label: http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/leaflet_EN6_12112007_web.pdf
- Food traceability factsheet: http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf
- Pesticide residues: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EU rules on wood packaging material: http://ec.europa.eu/food/plant/organisms/imports/overview_eu_rules.pdf
- Food contact materials - a practical guide: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/practical_guide_en.pdf
- Questions and answers on the regulation of GMOs in the EU: http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf
- GM guidelines for the European Food & Drink Industries: <http://www.ciaa.eu/documents/brochures/GM%20guidelines.pdf>
- EFSA guidance document on health claims: http://www.efsa.europa.eu/EFSA/ScientificPanels/NDA/efsa_locale-1178620753812_1178684448831.htm
- Vitamins & minerals – guidance on submissions for safety evaluations: http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf